PSJ3
Exhibit 491

Government & Public Policy Council
and
Specialty and Biotech Distributors Council Meeting

September 18, 2012

HDMA
Healthcare Distribution Management Association

Keith Flanagan

Senior Health Counsel
U.S. Senate Committee on Health, Education, Labor & Pensions (HELP)

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Pedigree - Federal

- Status of bi-cameral bipartisan staff discussions
- Progress
- Importance of the CA delegation
- Draft expectations
- Potential vehicles
- Timing

Pedigree - California

- Enforcement Committee Activity
- Stakeholder involvement and positions
- 2015-2017 approaching
- Impact on federal effort?
- Issues awaiting development/rule language

Pedigree Policy

- HDMA staff recommends we continue to advocate for a national solution
  - Is there a "deadline" for ending this effort or do we continue so long as the effort is viable? (manufacturers are contemplating whether the effort should extend beyond 2012 if necessary).
- HDMA staff recommends in California we continue to work toward implementation of the state's law and hold off on any policy shift. Monitor closely to determine what action is taken by other segments.
- Do HDMA members agree?

Rx Drug Abuse and Diversion

- Controlled Substances Task Force formed
- Goal – comprehensive policy and messaging encompassing federal and state legislative activity, regulatory, and public affairs
- First step – review of all ongoing issues and consideration of which to include in HDMA's legislative/public affairs "package"
- Is HDMA ready to be proactive, and how best can we leverage the positive efforts members have made?

Federal Issues

Recommend that we continue supporting:

- Increased penalties for cargo theft
- Interoperability standards and federal funding for PDMPs
- Increased penalties for pill mills
- Prohibition on wholesalers purchasing from pharmacies

Federal Issues, cont.

Model Federal Bill:

- Potential opportunity to proactively advocate for increased regulation and clarity on DEA expectations and/or for promoting our priority issues that we are already supporting
- Is this something we should pursue by outlining a potential framework for a model bill?

State Issues

Issues to consider:

- Doctor Shopping/Pill Mills
- Prohibition on Wholesalers Purchasing from Pharmacies
- Prescription Drug Monitoring Programs (PDMPs)
- E-prescribing

State Issues

Pill Mills/Doctor Shopping

- Recommend becoming more proactive in our support for legislation/regulation regarding pain clinic licensing and increased penalties.
- Also recommend supporting legislation/regulation prohibiting individuals from purchasing multiple prescriptions from different doctors.

State Issues

Prohibition on Wholesalers Purchasing from Pharmacies

- Recommend becoming more proactive, including potentially introducing state legislation/regulation, that prohibits wholesalers purchasing from pharmacies.
- Issues to address include returns and recent opposition from NCPA at the federal level.

State Issues

PDMPs

- Recommend becoming more vocal in our overall support of PDMPs.
- This includes support for federal funding and interoperability standards.
- NACDS and the AMA support PDMPs but they each have several concerns with issues including mandatory use and real-time reporting.

State Issues

E-prescribing

- Similar to PDMPs we recommend supporting the overall use of e-prescribing.
- NACDS has been more supportive of e-prescribing while NCPA has expressed concerns with the implementation costs for independent pharmacies.

Drug Abuse and Diversion - Other Issues

- Hydrocodone rescheduling
- Stronger wholesaler licensing requirements
- Controlled substances sales reporting
- Drug disposal
- Prescriber education

CS Abuse and Diversion Regulatory Options

Action	RAC Reaction	Rating
DEA Rule Petition	Enthusiastic: Low risk; Positive optics	
Update ICG	Low priority: If done, make it "high level"	
Collect ARCOS Data	Helpful but *significant* limitations: 100% participation needed but unlikely; "Huge effort"	
Distributors use PDMP data	Helpful but *significant* limitations: Most states have strict data access limits	
Customer algorithm/threshold	Not helpful: Analytics worse than ARCOS; additional concerns @ liability, anti-trust, etc.	
3rd party audit	Not helpful: Already have DEA audits; many have already had 3rd party audits	

= High Interest = Very Low Interest = Don't Do

Examples of Potential DEA Petition Contents

1. Clarify Existing CFR	• Define elements of "Suspicious Order" • How to measure Suspicious Orders
2. New CFR Requirements	• Define/clarify "Suspicious Customer" & "Pill Mill" • Clarify "due diligence" requirements
3. DEA Responsibilities*	• Requirements for investigating SO reports • Notify distributors of problem customers • Compliance warnings for distributors
4. Customer Responsibilities	• Define diversion/abuse prevention requirements for pharmacies, HCPs, etc. e.g., report certain info to DEA?

** May require some legislative changes*

CS Regulatory Follow-Up Options

Option 1 – HDMA could pursue petitioning DEA for a rulemaking.

Option 2 - HDMA could pursue the other options.

*Update ICG

*Gather ACROS Data

*Distributors use PDMPs

LIFO Repeal

Option 1: HDMA continues to remain categorically opposed LIFO repeal staying in league with NAW (as long as NAW remains categorically opposed to LIFO repeal)

Option 2: HDMA could broach the idea of a compromise (a la the Senator Kerry approach) with a move away from LIFO prospectively without the clawback of the reserves. While this does not have the fiscal impact that the Administration is looking for, does it move the U.S. towards harmonization?

Option 3: Trade LIFO for an acceptable reduction (% TBD?) in the corporate income tax rate. How is the correct rate determined?

LIFO Repeal

- Status of repeal efforts?
- Continue to monitor for any developments as deficit reduction, tax reform, etc. are contemplated
- HDMA staff recommends staying the course
  - May be too premature to start compromising
  - Lame duck and 113th Congress expectations

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Drug Shortages/Gray Market

Senate Commerce Committee

- Hearing held (7-25-12)
  - John Gray testified
  - Chairman Rockefeller (D-W.Va.) and Rep. Cummings (D-MD) release report on the gray market

House Oversight and Government Reform Cmte.

- Hearing held (11-30-11)
- Majority (Chairman Issa (R-CA)) report focusing on FDA's contribution to shortage issues (6-15-12)

House Energy and Commerce Health Subcommittee

- Hearing held (9-23-11) – John Gray testified

Drug Shortages/Gray Market

FDA Safety and Innovation (Public Law 112-144)

- No shortage reporting requirements for distributors

Senator Hatch's (R-Utah) Draft:

- For sterile injectable products with 4 or fewer manufacturers
  - ASP +6% to WAC
  - Freeze on 340B and Medicaid Rebates for 7 years
- FGAC recommends support – no action expected this year

Drug Shortages/Gray Market

Rep. Cummings legislation (H.R. 5853)

- Prohibition on wholesalers buying from pharmacies
- National wholesaler database
- State regulator information on wholesalers (to database)
- Sales price information on pedigrees

FGAC recommends support of the prohibition and has concerns with the other provisions

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ASP/Prompt Pay

Average Sales Price:

- Sequestration (1-1-13) – 2% cut in reimbursement
- Possibilities for further cuts as a pay-for during lame-duck discussions (fiscal cliff)

Prompt Pay:

H.R. 905 - 72 cosponsors/S. 733 – 3 cosponsors

- –Issues remain:
  - Cost of the provision
  - Pay-for

Reimbursement Issues

Status of AMP Rule

- Final rule expected in 2013
  - Presidential elections could impact timing
- CMS Continues to Publish FULs – 11 months
- HDMA commented:
  - Clarify bona fide service fees
  - Keep "presumed inclusion"
  - Ensure adequate pharmacy reimbursement
  - Provide AMP exclusions from 5i drugs
  - Focus on reducing FUL volatility

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Status of Sunshine Act Rule

- Last Official CMS Statement:
  - Final rule expected by the end of 2012
  - Data collection to begin by 1/1/13
- Roundtable Hearing on 9/12/12
  - "We (CMS) hope some of the data collection will occur in 2013"
  - Timeline for implementation
    - Stakeholders have differing opinions
  - Many clarifications are needed in the final rule
    - CMS might consider doing sub-regulatory guidance after releasing the final rule to provide additional clarification

HDMA's Comments on Sunshine Act

- HDMA comments focused on Congressional intent to exclude wholesalers and recommended:
  - Exclude repackagers, relabelers and kit assemblers from being an applicable manufacturer;
  - Exclude distributors that handle products made by a commonly owned company from "assistance and support" definitions to an applicable manufacturer; and
  - Exclude distributors from an applicable manufacturer.
- 5/24/12: HDMA Follow-up Letter to CMS

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Timeline on NADAC/NARP

2012 NADAC/NARP Activity	Date
NADAC/NARP Information Collection Submission to OMB	3/2/2012
CMS Met with HDMA	4/10/2012
Draft NADAC Methodology	5/31/2012
First NADAC Survey Letters	6/1/2012
Webinar on Draft NADAC Methodology	6/28/2012
Draft NARP Methodology	7/19/2012
Webinar on Draft NARP Methodology	7/26/2012
Final NADAC and NARP Methodologies	TBD
First Set of Draft NADAC and NARP Data	TBD
Webinar on First Set of Draft NADAC and NARP Data	TBD

HDMA's NADAC Focus

- Ensuring wholesalers do not have to report pricing data
  - Expect additional conversations with CMS and Myers and Stauffer
- Supporting appropriate pharmacy reimbursement
  - Dispensing Fee
  - A reasonable profit margin
- Ensuring confidentiality of submitted data

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Secondary NADAC Survey

- Committed to doing a secondary survey
  - Focus on off-invoice discounts, rebates, chargebacks and free goods
  - CMS plans to include more details about the process on its website
  - Anticipate a separate Federal Register Notice

Some Stakeholders' NADAC Concerns

- Statutory authority to collect data
- Confidentiality Issues
- Calculation Issues
- Updating of the NADAC
- Invoice Data Issues
- Burden of Data Collection
- Ensuring Appropriate Dispensing Fees

Some Stakeholders' NARP Concerns

- Statutory authority to collect data
  - Includes elements outside of the statute
- Sources of Data
  - Unnamed "Data Suppliers"
- Calculating the NARP
  - Estimation is being used
  - No accounting for uncollected copays
- Confusion from Disclosure of Numbers
  - The numbers won't comparable

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Alternative Reimbursement Options

Option 1 – Remain Neutral on NADAC Efforts

Option 2 – Support Predictive Acquisition Cost (PAC) Model

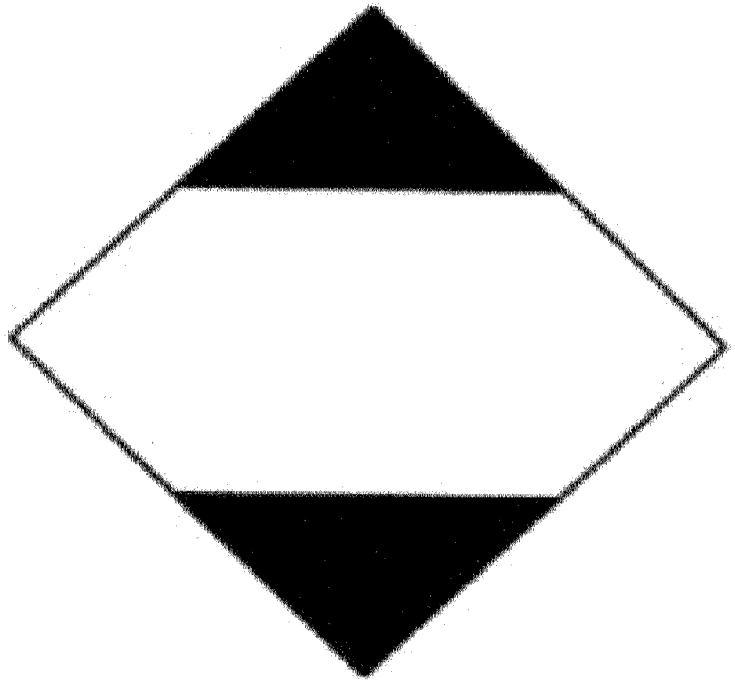
Option 3 – Develop a Non-Profit FICO-like Model

Regulatory Affairs

DOT Tote Marking Requirements

Current (since ~ 1990)

As of Dec. 31, 2013



Background - DOT Tote Markings

Late 2010 -- DOT proposes marking change; HDMA comments: don't change it

Early 2011 -- DOT requires new marking

Mid 2011 -- HDMA & DOT meet; HDMA requests continued (domestic) use of ORM-D totes

Mid 2012 -- DOT proposes 2-year extension; HDMA comments: support, but ask for more time

Why Oppose New Tote Marks?

- ✓ Expensive; requires tote replacement
- ✓ Int'l harmonization not needed
- ✓ Operational challenges, e.g.,
  - Retrieve old totes; replace with new
  - Storage space prior to removal
  - Ship to recycle/disposal
- ✓ Negative environmental impact; waste natural resources
- ✓ **No public health benefit!**

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DOT Follow-Up Options

Option 1 – Suggest DOT create exception for totes. (Some exceptions already exist)

Option 2 – Ask UPS to tell DOT their comments don't apply to totes.

Option 3 – Individual companies may apply for "Special Permit Process."

Option 4 – Do nothing. Wait for final rule.

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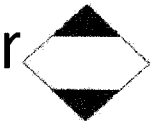
RAC likes 1,2, 3; note: They aren't mutually exclusive.

Option 1 Needs GPPC Review Because…

DOT interprets its regulations to require *something* hazardous in a tote if it's marked ORM-D or 

Con	Pro
• May bring attention to segregation issue • Would DOT take away existing exceptions?	• Precedent: Similar exclusions exist • Simultaneously resolves tote replacement and segregation issues • DOT already aware of segregation issues

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United States Pharmacopeial Convention (USP)

In January, USP released new Draft Chapter <1083> "*Good Distribution Practices - Supply Chain Integrity*"

Draft <1083> Concerns

- Imprecise language
- May confuse federal/state traceability efforts
- States may adopt/codify
- Committee* membership questionable:
  - Little/no applicable expertise
  - Conflict of interest
- Plans considerable guidance expansion

* USP's *General Chapters on Packaging, Storage and Distribution Expert Committee*

Good Distribution Practices

USP GC <1079> Good Distribution Practices – General Provisions

- <1079.1> *Good Warehousing Practices (e.g., inventory controls)*
- <1079.2> 1079.5>Good Wholesaler Practices
- <1079.3> Supply Agreements
- <1079.4>

USP GC <????> Good Supply Chain Controls

- <????.1> *Supply Chain Temp & Humidity Management*
- <????.2> *Excursions & Risk Management*
- <????.3> *Labeling*
- <????.4> *Container Closure Protection*
- <????.5>

USP GC <????> Good Importation & Exportation Practices

- <????.1> Good Procurement Practices
- <????.2> Good Importation Practices
- <????.3> Good Exportation Practices
- <????.4> International Distribution Practices
- <????.5> Custom Brokers
- <????.6>

USP GC <1083> Supply Chain Integrity

- <1083.1> Basic Guidance
- <1083.2> Pedigree
- <1083.3> Track & Trace
- <1083.4> Serialization
- <1083.5> GSI
- <1083. 6> Natural Disasters
- <1083.7>

Status

- HDMA expressed concerns (May)
  - Meeting with USP staff
  - USP's Workshop
- USP Webinar – Described expansion plans (June)
- HDMA seeking stakeholder support (since then)
  - Bio – Possible; meets with USP in Nov.
  - PhRMA – Possible; hears USP may back off; wants further info
  - GPhA – Initiated contact
  - NACDS – Unlikely; thinks USP has little/no impact
  - NCPA & APhA – Possible

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<1083> Options for Next Steps

Option 1 - Continue to seek stakeholder support; Jointly meet with USP to emphasize concerns

HDMA's preference if uncertainty about USP's plans continues

If stakeholders won't join HDMA

Option 2 - HDMA could meet with USP alone

Option 3 - HDMA could provide concerns in writing

Option 4 - No further action; wait for USP's next step

Advocacy and PAC Update

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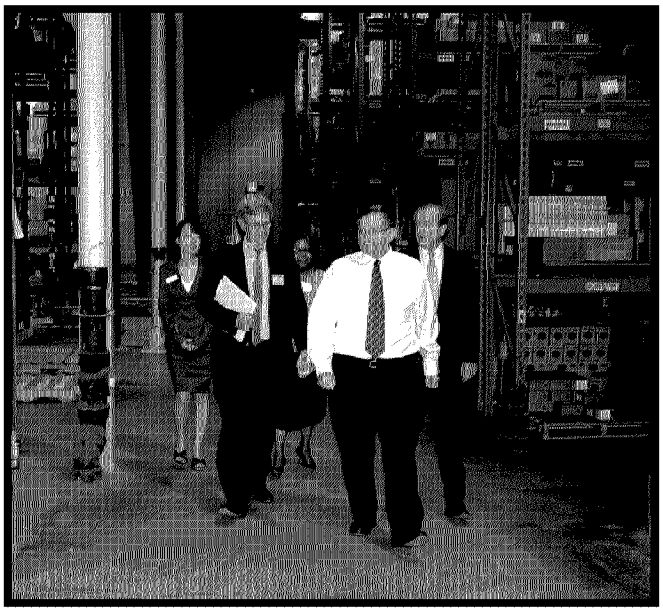
HDMA Advocacy

- **The Distribution Center Challenge**
  - HDMA advocacy initiative promoting distribution center tours for federal legislators during the fall Congressional Recess periods.



Mutual Drug Company hosts Congressman Brad Miller (D-N.C.)

- **Why August - October?**
  - Legislators are in the district as opposed to in DC; and
  - Legislators are more likely to accept an invitation to tour a facility they represent to learn more about the businesses operating in their district.
- **Why a distribution center tour?**
  - Develop relationships with legislators;
  - Face and name associated with a local business;
  - First-hand knowledge of the facility's capabilities and the value of healthcare distributors in the industry;
  - Mutually beneficial for legislator and business.

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HDMA Advocacy
Distribution Center Challenge

- Materials were distributed in early June to the FGAC and the HDMA Board.
- In August, the HDMA Weekly Digest began to feature tours held by companies participating in the challenge.
- Five HDMA member companies are participating to date, with additional legislative tours scheduled to take place over the next few weeks.
- We'd like to thank AmerisourceBergen, Cardinal Health, H.D. Smith, McKesson Corporation, and Top Rx for their participation in 2012.

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2012 HDMA PAC Contributors

The Chairman's Circle ($3,000-$5,000)

AmerisourceBergen Corporation PAC
Ann Bittman, HDMA
Cardinal Health, Inc. PAC
Express Scripts PAC
Terry Haas, Harvard Drug Group
Kristen LaRose Freitas, HDMA
Elizabeth Gallenagh, HDMA
John Gray, HDMA
Patrick Kelly, HDMA
McKesson Corp. Political Employees Fund
J. Christopher Smith, H.D. Smith

The President's Circle ($1,000-$2,999)

Dawn Boyter, Richie Pharmacal Co., LLC
Maria Burns, Burlington Drug Co.
Steven Collis, AmerisourceBergen Drug Co.
Ken Couch, Smith Drug Co.
Greg Drew, Value Drug Company
Anita Ducca, HDMA
Dennis Engel, KeySource Medical
Perry Fri, HDMA
Mike Kaufmann, Cardinal Health
Sam Lazich, DMS Pharmaceutical Group, Inc.
Joseph Mastandrea, Miami Luken, Inc.
David Moody, Mutual Wholesale Drug Co.
Albert Paonessa, III, Anda, Inc.
Tony Rattini, Miami Luken, Inc.
Karen Ribler, HDMA
GK Richards, Capital Wholesale Drug Co.
Raul Rodriguez Font, Drogueria Betances, Inc.
Ted Scherr, Dakota Drug
Nick Smock, PBA Health

PAC Member ($100-$999)

Dan Bellingham, HDMA
Linda Caporaletti Hoyt, HDMA
Mary Coppola, HDMA
Marjorie DePuy, HDMA
Anne Johnson, HDMA
Lisa Kanfer, HDMA
Elizabeth Lankford, HDMA
Tirza Lofgreen, HDMA
Brooke Naylor, HDMA
John Parker, HDMA
Ted Pezzullo, HDMA
Allison Wiley, HDMA

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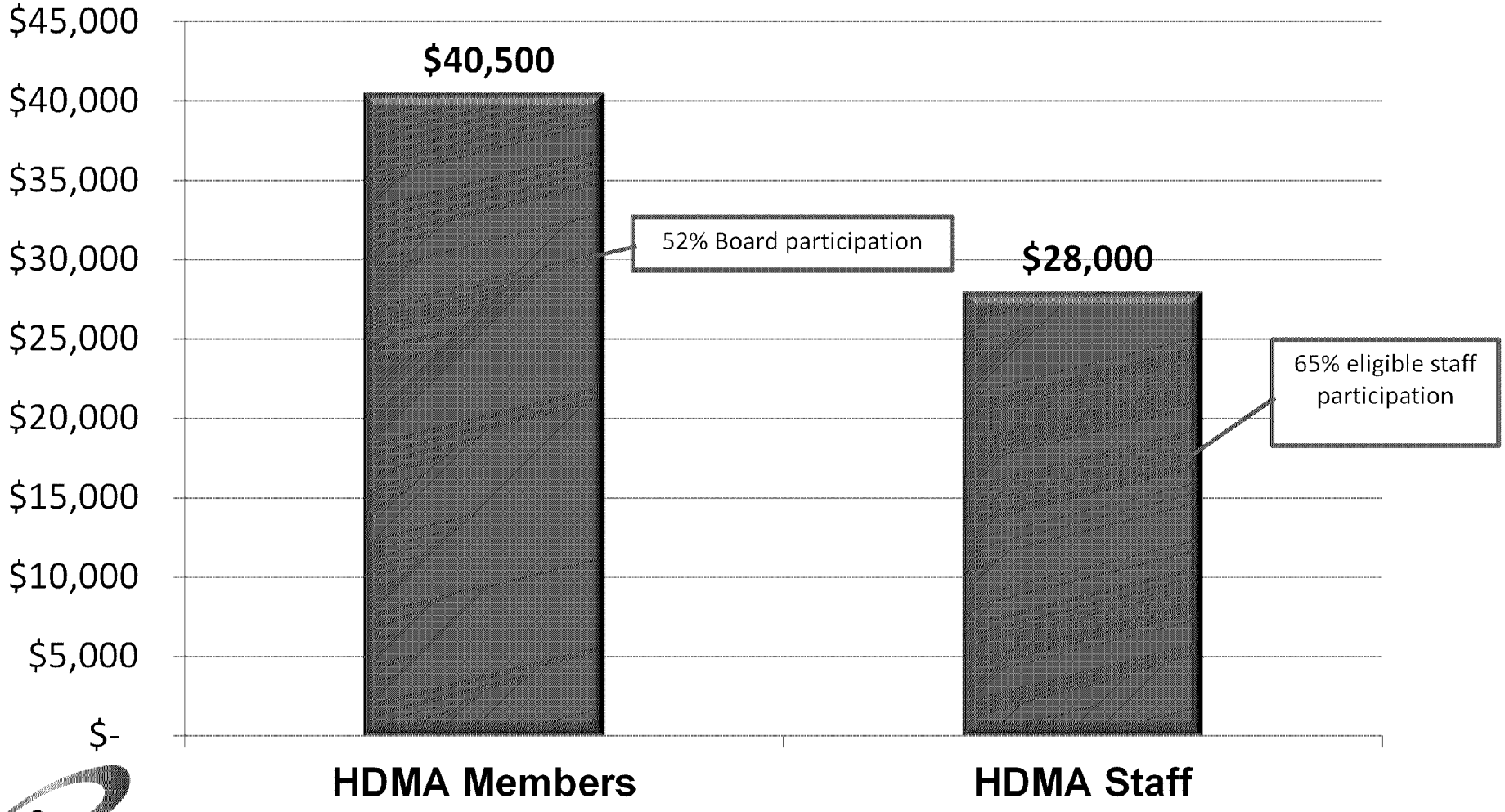
HDMA PAC

(2012 Projected Contributions)



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2012 PAC Update

(1-1-12 through 8-31-12)

Cash-on-hand: $33,000

Receipts: $61,500

Disbursements: $70,000

House of Representatives Candidates Supported

(2012 year-to-date)

Rep. Brian Bilbray (R-Calif.)
Rep. Marsha Blackburn (R-Tenn.)
Rep. John Boehner (R-Ohio)
Rep. Michael Burgess (R-Texas)
Rep. Dave Camp (R-Mich.)
Rep. Bill Cassidy (R-La.)
Rep. Diana DeGette (D-Colo.)
Rep. Jim Gerlach (R-Pa.)
Rep. Brett Guthrie (R-Ky.)
Rep. Ron Kind (D-Wis.)
Rep. Jim Matheson (D-Utah)
Rep. David McKinley (D-W.Va.)
Rep. Devin Nunes (R-Calif.)
Rep. Joe Pitts (R-Pa.)
Rep. Mike Rogers (R-Mich.)
Rep. Aaron Schock (R-Ill.)
Rep. John Shimkus (R-Ill.)
Rep. Patrick Tiberi (R-Ohio)
Rep. Fred Upton (R-Mich.)
Rep. Henry Waxman (D-Calif.)
Rep. Ed Whitfield (R-Ky.)
Republican Main Street Partnership PAC

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Senate Candidates Supported

(2012 year-to-date)

Sen. Max Baucus (D-Mont.)
Sen. Michael Bennet (D-Colo.)
Sen. Sherrod Brown (D-Ohio)
Sen. Tom Carper (D-Del.)
Sen. Bob Casey (D-Pa.)
Sen. Charles Grassley (R-Iowa)
Sen. Tom Harkin (D-Iowa)
Sen. Orrin Hatch (R-Utah)
Sen. Johnny Isakson (R-Ga.)
Sen. Joe Manchin (D-W.Va.)
Sen. Robert Menendez (D-N.J.)
Sen. Pat Roberts (R-Kan.)
Sen. Debbie Stabenow (D-Mich.)
Senate Moderate Democrats Political Action Committee

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Questions?